

REMARKS

Claims 1-26 are pending and under examination.

The rejection of claims 1-26 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement is respectfully traversed. Applicants respectfully maintain, for the reasons of record, that the specification provides sufficient description and guidance to enable the claimed methods.

As discussed in the previous response filed April 13, 2005, Applicants respectfully maintain that, based on the teachings in the specification and what was well known to those skilled in the art, one skilled in the art would have been able to make and use the invention as claimed. In the previous response, evidence was provided for the enablement of the claimed methods (Exhibits A-F). Exhibit A, Department of Health and Human Services (DHHS) Panel on Clinical Practices for Treatment of HIV Infection Guidelines, corroborates that the claimed methods provide advantages by increasing CD4⁺ T helper cell response (claim 2) and/or decreasing viral load or delaying an increase in viral load, consistent with the Guidelines. Exhibit B, Moss et al., Vaccine 21:1066-1071 (2003), showed that the immunized group had augmented HIV-specific T helper immune responses and β -chemokines after immunization and prior to antiviral drug treatment discontinuation. Exhibit C, Lichterfeld et al., J. Exp. Med. 200:701-712 (2004), showed that *in vivo* augmentation of virus-specific CD4⁺ T cell responses can lead to the reconstitution of HIV-1-specific CD8⁺ T cell lymphoproliferative immune responses *in vivo*. Exhibit D, Fernandez-Cruz et al., Vaccine 22:2966-2973 (2004), showed a delay of at least one year in virologic rebound in those receiving HIV immunogen compared to placebo and a 34% decrease in the risk of virologic failure. Exhibit E, abstract IAS05 presented at the Third IAS Conference on HIV Pathogenesis and Treatment in Rio de Janeiro July 24-27, 2005, showed that patients who received REMUNETM in both the STIR-2102 and the REMIT study were less likely to reach a study failure endpoint in 48 weeks of observation in the REMIT study compared to the other three groups and there was also a positive correlation between magnitude of HIV-specific immune responses and ability to delay virologic failure in these patients. Exhibit F, Gori et al. abstract presented at the Third IAS Conference on HIV Pathogenesis and Treatment in Rio de Janeiro July 24-27, 2005, showed that median absolute

CD4 cell counts remained stable through week 28 in the patients that received 3 injections of REMUNE™, but declined in both the IFA and saline groups.

For the reasons of record, based on the teachings in the specification and the corroborative evidence submitted with the previous response, Applicants respectfully maintain that the specification provides sufficient description and guidance to enable the claimed methods. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Applicants respectfully request consideration of the remarks above. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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